510(k) SUMMARY

K102781

Date Prepared: September 7, 2010

JAN 11 2011

Section 1 General Information

- **Applicant**

  Olympus Winter & Ibe GmbH
  Kuehnstrasse 61 * 22045 Hamburg * Germany
  Establishment Registration No: 9610773

- **Official Correspondent**

  Stacy Abbatiello Kluesner, M.S., RAC
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610
  Phone: 484-896-5405
  FAX: 484-896-7128
  Email: Stacy.Kluesner@Olympus.com
  Establishment Registration No.: 2429304

- **Manufacturer**

  Olympus Winter and Ibe GmbH
  Kuehnstrasse 61 * 22045 Hamburg * Germany
  Establishment Registration No.: 9610773

Section 2 Device Identification

Device Name: HF Electrosurgical Resection and Vaporization Electrode Series, for use with the Gyrus ACMI PK® PlasmaKinetic Superpulse System

Common Name: Electrosurgical Cutting & Coagulation & Accessories
Electrode, Electrosurgical, Active, Urological

Regulation Number: 21 CFR 878.4400
21 CFR 876.4300
21 CFR 876.1500

Regulation Name: Electrosurgical cutting and coagulation and accessories
Endoscopic electrosurgical unit and accessories

Regulatory Class: II

Product Code: FAS, GEI, FJL

Classification Panel: General and Plastic Surgery, Gastroenterology, and Urology

Section 3 Predicate Device Information

Predicate Devices for HF Resection Electrodes (Type H281)

510(k)	Device Name	Manufacturer
K100275	WA22302D, WA22503D, WA22306D, WA22507D, WA22521C, WA22523C, WA22351C, WA22355C	Olympus

Predicate Devices for HF Resection Button Electrode for Plasma Vaporization (Type H281)

510(k)	Device Name	Manufacturer
K100275	WA22557C	Olympus

Section 4 Device Description

The HF-Resection Electrodes and HF Resection Button Electrode for Plasma Vaporization consist of an active tip, PTFE color code identification, an insulator between the electrode and electrode tube, a guiding tube, telescope clip and arm (shaft).

The design and dimensions of the electrodes vary to accommodate various procedural conditions. The active tips of the various electrodes may consist of loops, bands, rollers, needles or buttons.

As an accessory the sterile device recognition cable is enclosed. The cable enables the use of the Gyrus ACMI PK®Superpulse System (K100816) with the Olympus HF Electrosurgical Resection and Vaporization Electrodes.

Section 5 Indications for Use

The HF-Resection Electrodes are a bipolar instrument series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and where hemostatis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedures for which the devices can be used are transurethral resection in saline (TURis), transurethral prostatectomy, transurethral resection of the prostate (TURP) for benign prostatic hyperplasia, transurethral incision of the prostate (TUIP) or bladder neck, transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment. These devices are not intended to be used to treating cancer of the prostate.

The HF-Resection Electrode for Plasma Vaporization is a bipolar instrument designed and intended for use in urological surgical procedures involving the vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostatis is required. The specific soft tissue indications include use in the prostate, bladder and bladder neck. The specific treatment indications include benign prostate hyperplasia BPH, bladder cancer, tumors, lesions and neoplasms. The specific urological indications include transurethral electrovaporization (TUVP, TVP, TUEVP), also known as transurethral vapor resection of the prostate (TUVRP) or transurethral vaporization in saline (TUVis). These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

Section 6 Comparison of Technological Characteristics

The HF Resection Electrodes and the HF Resection Button Electrode for Plasma Vaporization are basically identical to the predicate devices in intended use, design and material specifications.

Section 7 Conclusion

When compared to the predicate devices, HF Resection Electrodes and the HF Resection Button Electrode for Plasma Vaporization do not incorporate any significant changes that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Olympus Winter & Ibe GmbH
% Olympus America Inc.
Ms. Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
3500 Corporate Parkway, P.O. Box 610
Center Valley, Pennsylvania 18034-0610

JAN 11 2011

Re: K102781
Trade/Device Name: HF-Resection Electrode Series (Models WA22602D, WA22603D, WA22606D, WA22607D, WA22621C, WA22623C, WA22632D, WA22651C, WA22655C)
HF-Resection Electrode for Plasma Vaporization (Model WA22657C)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS, GEI
Dated: December 9, 2010
Received: December 13, 2010

Dear Ms. Abbatiello Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

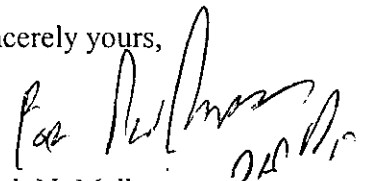
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K102781

510(k) Number (if known): JAN 11 2011

Device Name: HF-Resection Electrode Series

Model Numbers:
WA22602D, WA22603D, WA222606D, WA22607D, WA22621C, WA 22623C, WA22632D
WA22651C, WA22655C

Indications For Use:
The HF-Resection Electrodes are a bipolar instrument series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and where hemostatis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedures for which the devices can be used are transurethral resection in saline (TURis), transurethral prostatectomy, transurethral resection of the prostate (TURP) for benign prostatic hyperplasia, transurethral incision of the prostate (TUIP) or bladder neck, transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment.

These devices are not intended to be used to treating cancer of the prostate.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102781

Indications for Use

K102781

510(k) Number (if known):

Device Name: HF- Resection Electrode for Plasma Vaporization

JAN 11 2011

Model Number: WA22657C

Indications For Use:
The HF-Resection Electrode for Plasma Vaporization is a bipolar instrument designed and intended for use in urological surgical procedures involving the vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostatis is required. The specific soft tissue indications include use in the prostate, bladder and bladder neck. The specific treatment indications include benign prostate hyperplasia BPH, bladder cancer, tumors, lesions and neoplasms. The specific urological indications include transurethral electrovaporization (TUVP, TVP, TUEVP), also known as transurethral vapor resection of the prostate (TUVRP) or transurethral vaporization in saline (TUVis). These devices are intended to be used in an irrigated environment.

These devices are not intended to be used in treating cancer of the prostate.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102781